

Defendants.

JURY TRIAL DEMANDED

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

3. Upon information and belief, Defendant CVS Health Corporation (“CVS Health”) is a corporation organized under the laws of Delaware having a principal place of business in Woonsocket, Rhode Island.

Answer: Admitted.

4. Upon information and belief, Defendant CVS Pharmacy, Inc. (“CVS Pharmacy”) is a wholly-owned subsidiary of CVS Health, and is a corporation organized under the laws of Rhode Island having a principal place of business in Woonsocket, Rhode Island.

Answer: Admitted.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 because this action arises under the patent laws of the United States, including 35 U.S.C. § 271 *et seq.*

Answer: CVS admits that Plaintiffs purport to bring this action under the patent laws of the United States, Title 35 of the United States Code. CVS further admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

6. This Court has personal jurisdiction, general and specific, over Defendants because, among other things, Defendants are engaged in substantial and not isolated activity within this judicial district by regularly transacting business within this judicial district, regularly selling product within this judicial district, and deriving substantial revenues from sales in this judicial district. Also, Defendants have performed and continue to perform infringing activity, including selling the Accused Products, within this judicial district.

Answer: CVS does not contest personal jurisdiction in the United States District Court for the Southern District of New York solely for purposes of this action. Further response to the allegations is unnecessary. To the extent further response is necessary, CVS denies the remaining allegations.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

Answer: CVS does not contest venue in the United States District Court for the Southern District of New York solely for purposes of this action. Further response to the allegations is unnecessary. To the extent further response is necessary, CVS denies the remaining allegations.

NATURE OF THE ACTION

8. Plaintiffs own numerous patents, including the patents asserted in this Complaint, which cover compositions and formulations that include chromium picolinate in combination with other ingredients, such as nicotinic acid, ascorbic acid, citric acid and/or biotin, and their equivalents, and uses for such compositions and formulations. Upon information and belief, Defendants, and/or their agents, have received notice of and had knowledge of the patents asserted in this action.

Answer: CVS is without knowledge or information sufficient to admit or deny whether “Plaintiffs own numerous patents.” CVS denies the remaining allegations.

9. This civil action for patent infringement arises out of the activities of Defendants, and/or employees, divisions, subsidiaries, affiliates, agents and/or predecessor entities of Defendants (“Defendants”), in making, having made for their benefit, using, distributing, offering to sell, promoting, marketing, selling and/or importing into the United States nutritional and dietary supplements that combine chromium picolinate in combination with other ingredients,

such as nicotinic acid, niacinamide (amide of nicotinic acid), ascorbic acid, citric acid and/or biotin.

Answer: CVS admits that Plaintiffs purport to bring this action under the patent laws of the United States, and denies the remaining allegations.

10. Defendants, upon information and belief, have had made or made, offered for sale, sold, used, promoted, marketed, imported and/or distributed private label multivitamin and dietary supplements, including, for example, CVS private label multivitamins under the Spectravite brand name, which use chromium picolinate from suppliers other than Plaintiffs or their predecessors, in combination with other ingredients such as biotin, ascorbic acid, citric acid, niacinamide and/or nicotinic acid, or their equivalents, in violation of the asserted patents. Defendants, and/or their agents, upon information and belief, have knowledge of the asserted patents, and have undertaken the manufacture, marketing, promotion, offer for sale, sale and distribution of CVS private label vitamins and dietary supplements, including Spectravite multivitamins, with knowledge of their infringement, but without a license from Plaintiffs to use Plaintiffs' patented technology in Defendants' private label multivitamin and dietary supplement product lines, including Spectravite multivitamins. Defendants' making, having had made, using, distributing, offering for sale, selling, marketing, promoting and/or importing of Defendants' private label multivitamin and dietary supplements, including Spectravite multivitamins, purposefully and willfully infringed and continues to willfully infringe the asserted patents, directly and/or contributorily, and/or willfully induced others and continues to willfully induce others to infringe the asserted patents.

Answer: Denied.

THE PATENTS-IN-SUIT

11. Plaintiffs and Nutrition 21, Inc. (“N21”) are, inter alia, developers, marketers, sellers, and suppliers of efficacious, clinically substantiated ingredients to the nutritional and dietary supplement industry. Plaintiffs’ market segments include glucose metabolism and insulin resistance, appetite control and weight management. In particular, Plaintiffs and N21 researched, marketed, sold and sell a highly refined dietary form of chromium picolinate, under the brand Chromax®, to leading nutritional and dietary supplement manufacturers. Plaintiffs are small entities (as was N21) having intellectual property as one of their primary assets.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

12. Plaintiffs and N21 conceived and developed their intellectual property at much expense and effort, and have developed and maintained an extensive patent portfolio to cover its research, development and marketing of formulations comprising chromium picolinate in combination with other ingredients and compounds, such as, for example, biotin, ascorbic or citric acid, and/or nicotinic acid, and their equivalents, and uses for such formulations.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

13. For example, the United States Patent and Trademark Office (“USPTO”) duly and legally issued United States Patent No. 5,948,772 (“the ‘772 patent”), entitled “Chromium Picolinate Compositions and Uses Thereof” on September 7, 1999, to AMBI Inc., later known as N21. A true and correct copy of the ‘772 patent is attached as Exhibit A. JDS received by assignment all rights, title, and interest in and to the ‘772 patent, including the right to enforce and collect damages for all past, present and future infringements. By further agreement,

Nutrition 21 jointly owns the '772 patent with JDS as co-owners, whereby Nutrition 21 and JDS each have an equal and undivided one-half interest in all rights, title, and interest in and to the '772 patent, including the right to enforce and collect damages for all past, present and future infringements.

Answer: CVS admits that a document purporting to be a copy of United States Patent No. 5,948,772 is attached to the Complaint as Exhibit A. CVS is without knowledge or information sufficient to admit or deny the remaining allegations and therefore denies the same.

14. Also, the USPTO duly and legally issued United States Patent No. 6,136,317 ("the '317 patent"), entitled "Chromium Picolinate Compositions" on October 24, 2000, to AMBI Inc., later known as N21. A true and correct copy of the '317 patent is attached as Exhibit B. JDS received by assignment all rights, title, and interest in and to the '317 patent, including the right to enforce and collect damages for all past, present and future infringements. By further agreement, Nutrition 21 jointly owns the '317 patent with JDS as co-owners, whereby Nutrition 21 and JDS each have an equal and undivided one-half interest in all rights, title, and interest in and to the '317 patent, including the right to enforce and collect damages for all past, present and future infringements. The '317 patent is related to and claims priority to the '772 patent.

Answer: CVS admits that a document purporting to be a copy of United States Patent No. 6,136,317 is attached to the Complaint as Exhibit B. CVS is without knowledge or information sufficient to admit or deny the remaining allegations and therefore denies the same.

15. Additionally, the USPTO duly and legally issued United States Patent No. 6,251,889 ("the '889 patent"), entitled "Chromium Picolinate Compositions" on June 26, 2001 to AMBI Inc., later known as N21. A true and correct copy of the '889 patent is attached as Exhibit

C. JDS received by assignment all rights, title, and interest in and to the ‘889 patent, including the right to enforce and collect damages for all past, present and future infringements. By further agreement, Nutrition 21 jointly owns the ‘889 patent with JDS as co-owners, whereby Nutrition 21 and JDS each have an equal and undivided one-half interest in all rights, title, and interest in and to the ‘889 patent, including the right to enforce and collect damages for all past, present and future infringements. The ‘889 patent is related to and claims priority to the ‘772 patent.

Answer: CVS admits that a document purporting to be a copy of United States Patent No. 6,251,889 is attached to the Complaint as Exhibit C. CVS is without knowledge or information sufficient to admit or deny the remaining allegations and therefore denies the same.

16. And, the USPTO duly and legally issued United States Patent No. 6,143,301 (“the ‘301 patent”), entitled “Chromium Picolinate Compositions and Uses Thereof” on November 7, 2000, to AMBI Inc., later known as N21. A true and correct copy of the ‘301 patent is attached as Exhibit D. JDS received by assignment all rights, title, and interest in and to the ‘301 patent, including the right to enforce and collect damages for all past, present and future infringements. By further agreement, Nutrition 21 jointly owns the ‘301 patent with JDS as co-owners, whereby Nutrition 21 and JDS each have an equal and undivided one-half interest in all rights, title, and interest in and to the ‘301 patent, including the right to enforce and collect damages for all past, present and future infringements. The ‘301 patent is related to and claims priority to the ‘772 patent.

Answer: CVS admits that a document purporting to be a copy of United States Patent No. 6,143,301 is attached to the Complaint as Exhibit D. CVS is without knowledge or information sufficient to admit or deny the remaining allegations and therefore denies the same.

17. Still further, the USPTO duly and legally issued United States Reissue Patent No. 39,480 (“the Re ‘480 patent”), entitled “Chromium/Biotin Treatment of Type II Diabetes” on January 23, 2007, to N21. A true and correct copy of the Re ‘480 patent is attached as Exhibit E. The Re ‘480 patent is a reissue of United States Patent No. 5,929,066 (“the ‘066 patent”), the scope of claims 1-10 of the Re ‘480 patent being substantially identical, if not identical, to the scope of claims 1-10 of the ‘066 patent. JDS received by assignment all rights, title, and interest in and to the Re ‘480 patent, including the right to enforce and collect damages for all past, present and future infringements. By further agreement, Nutrition 21 jointly owns the Re ‘480 patent with JDS as co-owners, whereby Nutrition 21 and JDS each have an equal and undivided one-half interest in all rights, title, and interest in and to the Re ‘480 patent, including the right to enforce and collect damages for all past, present and future infringements.

Answer: CVS admits that a document purporting to be a copy of United States Reissue Patent No. 39,480 is attached to the Complaint as Exhibit E. CVS is without knowledge or information sufficient to admit or deny the remaining allegations and therefore denies the same.

18. The ‘772 patent, ‘317 patent, ‘889 patent, ‘301 patent, and Re ‘480 patent (collectively referred to as “the Patents-in-Suit”) relate to compositions comprising chromium picolinate in combination with other compounds, such as, for example, nicotinic acid, ascorbic acid, citric acid and/or biotin, and their equivalents, and methods for their use.

Answer: Denied. CVS refers to the patents’ claims for the content thereof.

19. The Patents-in-Suit are among approximately 20 patents and pending patent applications owned by Plaintiffs that concern compositions containing chromium and uses thereof.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

BACKGROUND

20. As an ingredient supplier, N21 sold Chromax® chromium picolinate to numerous customers who, in many circumstances, upon information and belief, incorporated Chromax® chromium picolinate into multiple product lines and SKUs, and even resold Chromax® chromium picolinate and/or compositions that contain Chromax® chromium picolinate with other ingredients to their customers as contract manufacturers. Many of N21's customers incorporated Chromax® chromium picolinate into dietary and nutritional supplements including multivitamins. Prior to 2009, and from 2009 through November 2011, N21 sold Chromax® chromium picolinate by weight and its price was dependent upon the volume (weight amount) of Chromax® chromium picolinate purchased by a customer.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

21. To support its sales, N21 sold its Chromax® chromium picolinate according to a business policy and practice that granted its customers a limited license under the Patents-in-Suit to use Chromax® chromium picolinate in their products and for uses covered by those patents. The fee for the limited license was bundled on an unallocated basis with the price that N21 charges to its customers for the Chromax® chromium picolinate product that N21 sold to them. When a customer purchased Chromax® chromium picolinate from N21 it received this limited license to use and practice the Patents-in-Suit, but only for the specific Chromax® chromium picolinate purchased from N21. Chromium picolinate purchased from other suppliers was not subject to this limited license.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

22. N21 promoted Chromax® chromium picolinate and its patent portfolio to the nutritional and dietary supplement industry. N21 worked with and educated one of its customers, Wyeth, Inc. (and its successors), the developer, maker, marketer, promoter and seller of Centrum® multivitamins, on the improved benefits of chromium picolinate, and compositions covered by its chromium picolinate patent portfolio; and as a result, the formulation for Centrum® multivitamins was improved to include, chromium picolinate in combination with, inter alia, biotin, niacinamide and ascorbic acid in or about May 2007. The change to chromium picolinate in combination with biotin, niacinamide and ascorbic acid was and is an important ingredient combination in Centrum® multivitamins.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

23. On or about November 22, 2011, N21 Acquisition Holding, LLC purchased certain assets and the Patents-in-Suit from N21, and further retained and employed key employees of N21. N21 Acquisition Holding, LLC later renamed itself JDS. By further agreement, Nutrition 21 jointly owns the Patents-in-Suit with JDS.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

24. Plaintiffs have continued the practice of selling Chromax® chromium picolinate by weight with its price dependent upon the volume (weight amount) of Chromax® chromium picolinate purchased by a customer. As an ingredient supplier, Nutrition 21 sells and has sold

Chromax® chromium picolinate to numerous customers who, in many circumstances, upon information and belief, incorporate Chromax® chromium picolinate into multiple product lines and SKUs, and even resell Chromax® chromium picolinate and/or compositions that contain Chromax® chromium picolinate with other ingredients to their customers as contract manufacturers.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

25. To support its sales, Nutrition 21 has sold and continues to sell its Chromax® chromium picolinate according to a business policy and practice that grants its customers a limited license under Nutrition 21's patents to use Chromax® chromium picolinate in their products and for uses covered by the Patents-in-Suit. The fee for the limited license continues to be bundled on an unallocated basis with the price that Nutrition 21 charges to its customers for the Chromax® chromium picolinate product that Nutrition 21 sells to them. When a customer purchases Chromax® chromium picolinate from Nutrition 21 it receives a limited license to use and practice the Patents-in-Suit, but only for the specific Chromax® chromium picolinate purchased from Nutrition 21. Chromium picolinate purchased from other suppliers is not and was not subject to this limited license.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

26. Defendants comprise a multi-billion dollar promoter and retail seller of brand name goods and private label goods, including dietary and nutritional supplements. Defendants have retail stores throughout the United States including in this district where they market, offer

to sell, sell and distribute, among other products and services, nutritional supplements, dietary supplements and/or multivitamins. On information and belief, Defendants make or have made at their request and according to their specifications, private label products which are a large part of Defendants' business in the United States. Upon information and belief, Defendants have made or have had made for their benefit or contracted for the manufacture of private label products, including private label multivitamins, including under the brand name Spectravite®, a multivitamin that copies the ingredients and dosages of the active ingredients used in Centrum® multivitamins.

Answer: Denied.

27. Over a period of years, Defendants, on information and belief, made, or had made on their request, for their benefit and according to their specification, and/or contracted for the manufacture of, CVS private label multivitamins, including Spectravite multivitamins that copy the active ingredients and dosages of several of Centrum® multivitamins. A number of these CVS private label multivitamins, including the Spectravite multivitamins, include chromium picolinate in combination with other ingredients such as biotin, ascorbic acid, citric acid, niacinamide and/or nicotinic acid, or their equivalents. Defendants advertise and promote that several of their Spectravite line of multivitamin products are equivalent to and comparable to the Centrum® line of products, relying on advertising, promotional materials, their website, product packaging and labels, and store positioning to promote the equivalence of Spectravite multivitamins to Centrum® multivitamins. For example, a prominent label on Defendants' Spectravite Adult 50+ products states "Compare to Centrum® Silver." Other Spectravite

multivitamins and labels use similar language directing potential Spectravite multivitamin customers to compare to other Centrum® multivitamins.

Answer: Denied.

28. Upon information and belief, Defendants, and/or their agents or manufacturer, do not purchase or use Chromax® chromium picolinate, but rather instead purchased and continue to purchase chromium picolinate from a supplier other than Plaintiffs, for use in their CVS private label multivitamins, including their Spectravite multivitamins. Defendants or Defendants' manufacturer purchased and used in CVS private label multivitamins, including their Spectravite multivitamins, chromic tripicolinate, referred to on the product label as chromium picolinate. In addition, a number of Defendants' private label multivitamins, including their Spectravite multivitamins, contain nicotinic acid, niacinamide, ascorbic acid, citric acid and/or biotin, or their equivalents, in combination with the chromium picolinate received from other suppliers and without license from Plaintiffs or N21. Defendants' making, having made for them, or contracting for its manufacture, offering for sale, selling, distributing, promoting, marketing, and/or importing CVS private label multivitamins, including the Spectravite multivitamins, without a license from Plaintiffs to use Plaintiffs' patented technology, purposefully and willfully infringed and continues to willfully infringe the Patents-in-Suit, directly and/or contributorily; and/or willfully induced others and continues to willfully induce others to infringe the Patents-in-Suit, literally and/or under the doctrine of equivalents.

Answer: Denied.

29. As a result of previous litigation, on or about March 8, 2014, Pfizer, Inc. settled a patent infringement action with Plaintiffs on its Centrum® multivitamin product line wherein

Pfizer acknowledged the validity of and took a license under the Patents-in-Suit (“Pfizer License”). The Pfizer License covering the use of chromium picolinate ingredient combinations in the Centrum® multivitamin product line was well publicized in the nutritional supplement market, including being reported in the Tan Sheet and Engredea, well known nutritional and dietary supplement trade publications. On March 11, 2014, Nutrition 21 sent a copy of a press release that announced the settlement and the license Pfizer received for Centrum® multivitamins under the Patents-in-Suit to known entities in the nutritional and dietary supplement industry.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

30. On or about April 15, 2014, Church & Dwight entered into a multi-year license with Nutrition 21 under the Patents-in-Suit for the use of chromium picolinate ingredient combinations in Church & Dwight’s dietary supplements including Vitafusion and L’il Critters nutritional supplements (the “Church & Dwight License”). The Church & Dwight License agreement was well publicized in the nutritional supplements market, including being reported in Engredea and Natural Products Insider, well known nutritional and dietary supplement trade publications. On April 22, 2014, Nutrition 21 sent a copy of a press release that announced the license Church & Dwight received for their Vitafusion and L’il Critters nutritional supplements under the Patents-in-Suit to known entities in the nutritional and dietary supplement industry.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

31. On or about February 24, 2015, Schwabe North America and Nature's Way paid Plaintiffs for a multi-year license ("Nature's Way License") under the Patents-in-Suit for the use of chromium picolinate ingredient combinations in its Alive® multivitamins. Schwabe North America and Nature's Way also acknowledged the validity of the Patents-in-Suit. On or about March 3, 2015, Nutrition 21 sent a copy of a press release that announced the license that Schwabe North America and Nature's Way received to the Patents-in-Suit for their Alive® multivitamin and nutritional supplements to known entities in the nutritional and dietary supplement industry, including many contract manufacturers, who, upon information and belief, make Spectravite Products for the Defendants. The Nature's Way License was well reported in the nutritional supplements market, including a March 4, 2015 article in Nutra-Ingredients-USA.com, a well-known nutritional and dietary supplement trade publication, that referenced the "Pfizer License" for Centrum® multivitamins under the Patents-in-Suit.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations and therefore denies the same.

32. Upon information and belief, and based upon the well-publicized nature of the Pfizer License wherein Pfizer took a license for Centrum® multivitamins under the Patents-in-Suit, Defendants and/or their agents knew of or were willfully blind as to the existence of the Patents-in-Suit.

Answer: Denied.

33. As described in more detail below, Defendants engaged in behavior purposely designed and orchestrated to violate Plaintiffs' patent rights. In so doing, Defendants willfully and intentionally violated and infringed the patent rights owned by Plaintiffs. As a result of

Defendants' actions, Plaintiffs have been severely damaged by Defendants' willful and deliberate infringement of the Patents-in-Suit as described in more detail below.

Answer: Denied.

COUNT I: INFRINGEMENT OF THE '772 PATENT

34. Plaintiffs reallege and incorporate herein by reference the preceding paragraphs as though fully set forth herein.

Answer: CVS incorporates herein by reference its responses to the preceding paragraphs as though fully set forth herein.

35. Defendants among other things, make, have made for them, use, offer for sale, sell, market, promote, distribute and/or import within the United States, now and in the past, multivitamins and dietary supplements, such as, for example, products that contain chromium picolinate in combination with niacinamide and/or nicotinic acid. Exemplary products made and/or sold by Defendants that include chromium picolinate in combination with nicotinic acid and/or niacinamide include a number of CVS private label multivitamins, including Spectravite multivitamins, including, but not limited to, Spectravite Adult Multivitamin, Spectravite Ultra Women Multivitamin, Spectravite Ultra Men Multivitamin, Spectravite Adult 50+ Multivitamin, Spectravite Ultra Men 50+ Multivitamin, Spectravite Ultra Women 50+ Multivitamin (hereinafter collectively the "Spectravite Products"), CVS Women's Multivitamin/Multimineral, CVS Men's Multivitamin/Multimineral and CVS Diabetes Health Support supplements (collectively the "CVS Private Label Products"). Discovery may uncover other products made, made for them, used, offered for sale, sold, marketed, promoted, imported, and/or distributed by the Defendants, now and in the past, that include chromium picolinate in combination with nicotinic acid, or its equivalent, that may infringe the '772 patent. In addition, Defendants among

other things, have created, distributed and continue to create and distribute suggested instructions for use, labels and marketing materials for such CVS Private Label Products, and have promoted the sale of and sold, now and in the past, and continue to promote the sale of and sell such CVS Private Label Products to end users and customers.

Answer: Denied.

36. On information and belief, Defendants directly or indirectly through the actions of other entities, have infringed, now and in the past, and continue to infringe the '772 patent directly, indirectly (by inducing or contributing to the infringement by others), jointly, literally and/or equivalently, by, among other things, making, having made for them, using, marketing, distributing, selling, offering for sale, promoting, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products that embody, or include instructions and product labels encouraging the practice of, at least one of claims 1, 8 and 15 of the '772 patent.

Answer: Denied.

37. On information and belief, Defendants have, and/or their agents and contract manufacturers have, infringed, now and in the past, and continue to infringe the '772 patent directly, jointly, literally and/or equivalently, by, among other things, making, having made for them, using, distributing, selling, offering for sale, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products, which contain chromium picolinate in combination with niacinamide and/or nicotinic acid, or its equivalent, that embody at least claim 1 of the '772 patent. Upon information and belief, Defendants have contract manufacturers and/or other agents

make for them, and according to specifications known to and specified by them, the CVS Private Label Products, including the Spectravite Products that are sold as equivalent to and intended to match the active ingredients and dosage amounts in Centrum® brand multivitamins.

Answer: Denied.

38. On information and belief, end users and consumers take CVS Private Label Products according to their suggested instructions of orally ingesting them. End users and consumers have infringed, now and in the past, and continue to infringe at least one of claims 1, 8 and 15 of the ‘772 patent directly, jointly, literally and/or by equivalents by using the CVS Private Label Products in the United States in a manner that practices at least one of claims 1, 8 and 15 of the ‘772 patent.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations regarding end users’ and consumers’ ingestion, and denies the remaining allegations.

39. On information and belief, Defendants, and/or their agents and contract manufacturers, had and continue to have actual and constructive knowledge of and are aware of or willfully blind to the Patents-in-Suit, including the ‘772 patent. Plaintiffs have notified the industry of the Patents-in-Suit and its settlement of a patent infringement action with, and license of the ‘772 patent to, Pfizer for its Centrum® multivitamins, the same Centrum® multivitamins that the Defendants have copied with their Spectravite Products and that the Defendants direct consumers to compare with their Spectravite Products.

Answer: Denied.

40. With knowledge of the ‘772 patent and the specific intent to encourage, promote, instruct, contribute to and induce the infringement of the ‘772 patent, Defendants have infringed,

now and in the past, and continue to infringe at least one of claims 1, 8 and 15 of the '772 patent, indirectly, jointly, literally and/or by equivalents, by, among other things, encouraging, promoting, instructing, teaching, contributing to and inducing end users and customers to infringe at least one of claims 1, 8 and 15 of the '772 patent by, among other things, (1) making, having made for them, using, offering for sale, selling, distributing, marketing and/or importing within the United States, now and in the past, the CVS Private Label Products, and (2) creating and distributing suggested instructions for use, labels and promotional advertising materials that Defendants knew, and continue to know, encourages, promotes, instructs, teaches, contributes to and induces use of the CVS Private Label Products, now and in the past, in a manner that Defendants knew, and continue to know, practices at least one of claims 1, 8 and 15 of the '772 patent. For example, Defendants, with knowledge of the '772 patent, make, have made for them, distribute, market, promote, offer for sale, sell and/or import into the United States, now and in the past, the CVS Private Label Products, and created, provided, and continue to create and provide, instructions of use for consumers of their CVS Private Label Products, and otherwise promote and market such products, now and in the past, such that customers and end users orally take and use the CVS Private Label Products according to Defendants' instructions and in a manner that Defendants knew, and continue to know, practices at least one of claims 1, 8 and 15 of the '772 patent.

Answer: Denied.

41. On information and belief, Defendants' nutritional supplements and/or multivitamins, including but not limited to, the CVS Private Label Products, now and in the past, are specifically made to be taken orally, are a material part of the method of at least one of claims

8 and 15 of the '772 patent, and are not staple articles nor commodities of commerce suitable for substantial non-infringing uses.

Answer: Denied.

42. At the very least, Defendants were, and/or their agents and contract manufacturers were, willfully blind as to the existence of the '772 patent, and/or willfully blinded themselves to end users' direct infringement of the '772 patent as a result of end users' use of the CVS Private Label Products in a manner that follows the suggested use of the CVS Private Label Products on the product label, whereby the Defendants' instructions and promotional activities encourage promote, instruct, and teach methods and uses, now and in the past, that meet at least the limitations of at least one of claims 1, 8 and 15 of the '772 patent.

Answer: Denied.

43. On information and belief, Defendants, and/or their agents and contract manufacturers, knew of the '772 patent, ignored and/or disregarded that their actions constituted infringement of a valid patent, and acted despite an objectively high likelihood that their actions constituted infringement of the '772 patent, and therefore Defendants' infringement is and has been willful, wanton, deliberate and without license, thereby rendering this case exceptional within the meaning of 35 U.S.C. §§ 284 and 285.

Answer: Denied.

44. Defendants' acts have caused and will continue to cause irreparable harm and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

Answer: Denied.

45. Unless preliminarily and permanently enjoined, Defendants have and will continue to infringe the ‘772 patent to Plaintiffs’ substantial and irreparable harm.

Answer: Denied.

COUNT II: INFRINGEMENT OF THE ‘317 PATENT

46. Plaintiffs reallege and incorporate herein by reference the preceding paragraphs as though fully set forth herein.

Answer: CVS incorporates herein by reference its responses to the preceding paragraphs as though fully set forth herein.

47. Defendants, among other things, make, have made for them, use, offer for sale, sell, market, promote, distribute and/or import within the United States, now and in the past, multivitamins and dietary supplements, such as, for example, products that contain chromium picolinate in combination with niacinamide and/or nicotinic acid. Exemplary products made and/or sold by Defendants that include chromium picolinate in combination with nicotinic acid and/or niacinamide include, but are not necessarily limited to, the CVS Private Label Products. Discovery may uncover other products made, made for them, used, offered for sale, sold, distributed, marketed, promoted, and/or imported by the Defendants, now and in the past, that include chromium picolinate in combination with nicotinic acid, or its equivalent, that may infringe the ‘317 patent. In addition, Defendants among other things, have created, distributed and continue to create and distribute suggested instructions for use, labels and marketing material for such CVS Private Label Products, and have promoted the sale of and sold, now and in the past, and continue to promote the sale of and sell such CVS Private Label Products to end users and customers.

Answer: Denied.

48. On information and belief, Defendants directly or indirectly through the actions of other entities, have infringed, now and in the past, and continue to infringe the '317 patent directly, indirectly (by inducing or contributing to the infringement by others), jointly, literally and/or equivalently, by, among other things, making, having made for them, using, marketing, distributing, selling, offering for sale, promoting, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products that embody, or include instructions and product labels encouraging the practice of, at least one of claims 12, 33 and 49 of the '317 patent.

Answer: Denied.

49. On information and belief, Defendants have, and/or their agents and contract manufacturers have, infringed, now and in the past, and continue to infringe the '317 patent directly, jointly, literally and/or equivalently, by, among other things, making, having made for them, using, distributing, offering for sale, selling and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products, which contain chromium picolinate in combination with niacinamide and/or nicotinic acid, or its equivalent, that embody at least claim 12 of the '317 patent. Upon information and belief, Defendants have contract manufacturers and/or other agents make for them, and according to specifications known to and specified by them, the CVS Private Label Products, including the Spectravite Products that are sold as equivalent to and which are intended to match the active ingredients and dosage amounts in Centrum® brand multivitamins.

Answer: Denied.

50. On information and belief, end users and consumers take the CVS Private Label Products according to their suggested instructions of orally ingesting them. End users and consumers have infringed, now and in the past, and continue to infringe at least one of claims 12, 33 and 49 of the '317 patent directly, jointly, literally and/or by equivalents by using the CVS Private Label Products in the United States in a manner that practices at least one of claims 12, 33 and 49 of the '317 patent.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations regarding end users' and consumers' ingestion, and denies the remaining allegations.

51. On information and belief, Defendants, and/or their agents and contract manufacturers, had and continue to have actual and constructive knowledge of and are aware of or willfully blind to the Patents-in-Suit, including the '317 patent. Plaintiffs have notified the industry of the Patents-in-Suit and its settlement of a patent infringement action with, and license of the '317 patent to, Pfizer for its Centrum® multivitamins on which the Spectravite Products are based and on which the Defendants direct consumers to compare with their Spectravite Products.

Answer: Denied.

52. With knowledge of the '317 patent and the specific intent to encourage, promote, instruct, contribute to and induce the infringement of the '317 patent, Defendants have infringed, now and in the past, and continue to infringe at least one of claims 12, 33 and 49 of the '317 patent, indirectly, jointly, literally and/or by equivalents, by, among other things, encouraging, promoting, instructing, teaching, contributing to and inducing end users and customers to infringe at least one of claims 12, 33 and 49 of the '317 patent by, among other things, (1)

making, having made for them, using, offering for sale, selling, distributing, marketing and/or importing within the United States, now and in the past, the CVS Private Label Products, and (2) creating and distributing suggested instructions for use, labels and promotional advertising materials that Defendants knew, and continue to know, encourages, promotes, instructs, teaches, contributes to and induces use of the CVS Private Label Products, now and in the past, in a manner that Defendants knew, and continue to know, practices at least one of claims 12, 33 and 49 of the '317 patent. For example, Defendants with knowledge of the '317 patent, make, have made for them, distribute, market, promote, offer for sale, sell and/or import into the United States, now and in the past, the CVS Private Label Products, and created, provided, and continue to create and provide instructions of use for consumers of its CVS Private Label Products, and otherwise promote and market such products, now and in the past, such that customers and end users orally take and use the CVS Private Label Products according to Defendants' instructions and in a manner that Defendants know, and continue to know, practices at least one of claims 12, 33 and 49 of the '317 patent.

Answer: Denied.

53. On information and belief, Defendants' nutritional supplements and/or multivitamins, including but not limited to, the CVS Private Label Products, now and in the past, are specifically made to be taken orally, are a material part of the method of at least one of claims 33 and 49 of the '317 patent and are not staple articles nor commodities of commerce suitable for substantial non-infringing uses.

Answer: Denied.

54. At the very least, Defendants were, and/or their agents and contract manufacturers were, willfully blind as to the existence of the '317 patent, and/or willfully blinded themselves to end users' direct infringement of the '317 patent as a result of end users' use of the CVS Private Label Products in a manner that follows the suggested use of the CVS Private Label Products on the product labels, whereby the Defendants' instructions and promotional activities encourage, promote, instruct, and teach methods and uses, now and in the past, that meet at least the limitations of at least one of claims 12, 33 and 49 of the '317 patent.

Answer: Denied.

55. On information and belief, Defendants, and/or their agents and contract manufacturers, knew of the '317 patent, ignored and/or disregarded that their actions constituted infringement of a valid patent, and acted despite an objectively high likelihood that their actions constituted infringement of the '317 patent, and therefore Defendants' infringement is and has been willful, wanton, deliberate and without license, thereby rendering this case exceptional within the meaning of 35 U.S.C. §§ 284 and 285.

Answer: Denied.

56. Defendants' acts have caused and will continue to cause irreparable harm and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

Answer: Denied.

57. Unless preliminarily and permanently enjoined, Defendants have and will continue to infringe the '317 patent to Plaintiffs' substantial and irreparable harm.

Answer: Denied.

COUNT III: INFRINGEMENT OF THE '889 PATENT

58. Plaintiffs reallege and incorporate herein by reference the preceding paragraphs as though fully set forth herein.

Answer: CVS incorporates herein by reference its responses to the preceding paragraphs as though fully set forth herein.

59. Defendants, among other things, make, have made for them, use, offer for sale, sell, market, promote, distribute and/or import within the United States, now and in the past, multivitamins and dietary supplements, such as, for example, products that contain chromium picolinate in combination with niacinamide and/or nicotinic acid. Exemplary products made and/or sold by Defendants that include chromium picolinate in combination with nicotinic acid and/or niacinamide include, but are not necessarily limited to, the CVS Private Label Products. Discovery may uncover other products made, made for it, used, offered for sale, sold, distributed, marketed, promoted and/or imported by the Defendants, now and in the past, that include chromium picolinate in combination with nicotinic acid, or its equivalent, that may infringe the '889 patent. In addition, Defendants, among other things, have created, distributed and continue to create and distribute suggested instructions for use, labels and marketing materials for such CVS Private Label Products, and have promoted the sale of and sold, now and in the past, and continue to promote the sale of and sell such CVS Private Label Products to end users and customers.

Answer: Denied.

60. On information and belief, Defendants directly or indirectly through the actions of other entities, have infringed, now and in the past, and continue to infringe the '889 patent directly, indirectly (by inducing or contributing to the infringement by others), jointly, literally

and/or equivalently, by, among other things, making, having made for them, using, marketing, distributing, selling, offering for sale, promoting, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products that embody, or include instructions and product labels encouraging the practice of, at least claim 9 of the '889 patent.

Answer: Denied.

61. On information and belief, Defendants have, and/or their agents and contract manufacturers have, infringed, now and in the past, and continue to infringe at least claim 9 of the '889 patent directly, jointly, literally and/or equivalently, by, among other things, making, having made for them, using, distributing, marketing, promoting, offering for sale, selling and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products that contain chromium picolinate in combination with niacinamide and/or nicotinic acid, or its equivalents, that embody at least claim 9 of the '889 patent. Upon information and belief, Defendants have contract manufactures and/or other agents make for them, and according to specifications known to and specified by them, the CVS Private Label Products, including the Spectravite Products that are sold as equivalent to the active ingredients and dosage amounts in the Centrum® brand multivitamins.

Answer: Denied.

62. On information and belief, end users and consumers take the CVS Private Label Products according to their suggested instructions of orally ingesting them. End users and consumers have infringed, now and in the past, and continue to infringe at least claim 9 of the

‘889 patent directly, jointly, literally and/or by equivalents by using the CVS Private Label Products in the United States in a manner that practices at least claim 9 of the ‘889 patent.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations regarding end users’ and consumers’ ingestion, and denies the remaining allegations.

63. On information and belief, Defendants, and/or their agents and contract manufacturers, had and continue to have actual and constructive knowledge of and are aware of or willfully blind to the Patents-in-Suit, including the ‘889 patent. Plaintiffs have notified the industry of the Patents-in-Suit and its settlement of a patent infringement action with, and license of the ‘889 patent to, Pfizer for its Centrum® multivitamins on which the Spectravite Products are based and on which the Defendants direct consumers to compare with their Spectravite Products.

Answer: Denied.

64. With knowledge of the ‘889 patent and the specific intent to encourage, promote, instruct, contribute to and induce the infringement of the ‘889 patent, Defendants have infringed, now and in the past, and continue to infringe at least claim 9 of the ‘889 patent, indirectly, jointly, literally and/or by equivalents, by, among other things, encouraging, promoting, instructing, teaching, contributing to and inducing end users and customers to infringe at least claim 9 of the ‘889 patent by, among other things, (1) making, having made for them, using, offering for sale, selling, distributing, marketing and/or importing within the United States, now and in the past, CVS Private Label Products, and (2) creating and distributing suggested instructions for use, labels and promotional advertising materials that Defendants knew and continue to know, encourages, promotes, instructs, teaches, contributes to and induces use of the CVS Private Label

Products, now and in the past, in a manner that Defendants knew, and continue to know, practices the method of at least claim 9 of the '889 patent. For example, Defendants, with knowledge of the '317 patent, make, have made for them, distribute, market, promote, offer for sale, sell and/or import into the United States, now and in the past, the CVS Private Label Products, and created, provided, and continue to create and provide, instructions of use for consumers of their CVS Private Label Products, and otherwise promote and market such products, now and in the past, such that customers and end users orally take and use the CVS Private Label Products according to Defendants' instructions and in a manner that the Defendants knew, and continue to know, practices at least the method of claim 9 of the '889 patent.

Answer: Denied.

65. On information and belief, Defendants' nutritional supplements and/or multivitamins, including but not limited to, the CVS Private Label Products, now and in the past, are specifically made to be taken orally, are a material part of the method of at least claim 9 of the '889 patent, and are not staple articles nor commodities of commerce suitable for substantial non-infringing uses.

Answer: Denied.

66. At the very least, Defendants were, and/or its agents and contract manufacturers were, willfully blind as to the existence of the '889 patent, and/or willfully blinded themselves to end users' direct infringement of the '889 patent as a result of end users' use of the CVS Private Label Products in a manner that follows the suggested use of the CVS Private Label Products on the product labels, whereby the Defendants' instructions and promotional activities encourage,

promote, instruct, and teach methods and uses, now and in the past, that meet at least the limitations of claim 9 of the '889 patent.

Answer: Denied.

67. On information and belief, Defendants, and/or their agents and contract manufacturers, knew of the '889 patent, ignored and/or disregarded that its actions constituted infringement of a valid patent, and acted despite an objectively high likelihood that their actions constituted infringement of the '889 patent, and therefore Defendants' infringement is and has been willful, wanton, deliberate and without license, thereby rendering this case exceptional within the meaning of 35 U.S.C. §§ 284 and 285.

Answer: Denied.

68. Defendants' acts have caused and will continue to cause irreparable harm and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

Answer: Denied.

69. Unless preliminarily and permanently enjoined, Defendants have been and will continue to infringe the '889 patent to Plaintiffs' substantial and irreparable harm.

Answer: Denied.

COUNT IV: INFRINGEMENT OF THE '301 PATENT

70. Plaintiffs reallege and incorporate herein by reference the preceding paragraphs as though fully set forth herein.

Answer: CVS incorporates herein by reference its responses to the preceding paragraphs as though fully set forth herein.

71. Defendants, among other things, make, have made for them, use, offer for sale, sell, market, promote, distribute and/or import within the United States, now and in the past,

multivitamins and dietary supplements, such as, for example, products that contain chromium picolinate in combination with ascorbic acid or citric acid. Exemplary Products made and/or sold by Defendant that include chromium picolinate in combination with ascorbic acid and/or citric acid, or their equivalents, include, but are not necessarily limited to, the CVS Private Label Products. Discovery may uncover other products made, made for them, used, offered for sale, sold, distributed, marketed, promoted and/or imported by the Defendants, now and in the past, that include chromium picolinate in combination with ascorbic acid and/or citric acid, or their equivalents, that may infringe the '301 patent. In addition, Defendants, among other things, have created, distributed and continue to create and distribute suggested instructions for use, labels and marketing materials for such CVS Private Label Products, and have promoted the sale of and sold, now and in the past, and continue to promote the sale of and sell such CVS Private Label Products to end users and customers.

Answer: Denied.

72. On information and belief, Defendants directly or indirectly through the actions of other entities, have infringed, now and in the past, and continue to infringe the '301 patent directly, indirectly (by inducing or contributing to the infringement by others), jointly, literally and/or equivalently, by, among other things, making, having made for them, using, marketing, selling, distributing, offering for sale, promoting, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products, that embody, or include instructions and product labels encouraging the practice of, at least one of claims 21, 27 and 33 of the '301 patent.

Answer: Denied.

73. On information and belief, Defendants have, and/or their agents and contract manufacturers have, infringed, now and in the past, and continue to infringe the '301 patent directly, jointly, literally and/or equivalents, by, among other things, making, having made for them, distributing, marketing, using, promoting, selling, offering for sale, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Products, which contain chromium picolinate in combination with ascorbic acid or citric acid, or their equivalents, that embody at least claim 21 of the '301 patent. Upon information and belief, Defendants have contract manufacturers and/or other agents make for them, and according to specifications known to and specified by them, the CVS Private Label Products, including the Spectravite Products that are sold as equivalent to and which are intended to match the active ingredients and dosage amounts in Centrum® brand multivitamins.

Answer: Denied.

74. On information and belief, end users and consumers take the CVS Private Label Products according to their suggested instructions of orally ingesting them. End users and consumers have infringed, now and in the past, and continue to infringe at least one of claims 21, 27 and 33 of the '301 patent directly, jointly, literally and/or by equivalents by using the CVS Private Label Products in the United States in a manner that practices at least one of claims 21, 27 and 33 of the '301 patent.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations regarding end users' and consumers' ingestion, and denies the remaining allegations.

75. On information and belief, Defendants, and/or their agents and contract manufacturers, had and continue to have actual and constructive knowledge of and are aware of or willfully blind to the Patents-in-Suit, including the '301 patent. Plaintiffs have notified the industry of the Patents-in-Suit and its settlement of a patent infringement action with, and license of the '301 patent to, Pfizer for its Centrum® multivitamins on which the Spectravite Products are based and on which the Defendants direct consumers to compare with its Spectravite Products.

Answer: Denied.

76. With knowledge of the '301 patent and the specific intent to encourage, promote, instruct, contribute to and induce the infringement of the '301 patent, Defendants have infringed, now and in the past, and continue to infringe at least one of claims 21, 27 and 33 of the '301 patent, indirectly, jointly, literally and/or by equivalents, by, among other things, encouraging, promoting, instructing, teaching, contributing to and inducing end users and customers to infringe at least one of claims 21, 27 and 33 of the '301 patent by, among other things, (1) making, having made for them, using, offering for sale, selling, distributing, marketing and/or importing within the United States, now or in the past, the CVS Private Label Products, and (2) creating and distributing suggested instructions for use, labels and promotional advertising materials that Defendants know and continue to know, encourages, promotes, instructs, teaches, contributes to and induces use of the CVS Private Label Products, now and in the past, in a manner that Defendants know, and continue to know, practices at least one of claims 21, 27 and 33 of the '301 patent. For example, Defendants, with knowledge of the '301 patent, make, have made for them, distribute, market, promote, offer for sale, sell and/or import into the United

States, now and in the past, the CVS Private Label Products, and created, provided, and continues to create and provide, instructions of use for consumers of their CVS Private Label Products, and otherwise promote and market such products, now and in the past, such that customers and end users orally take and use the CVS Private Label Products according to Defendants' instructions and in a manner that the Defendants knew, and continue to know, practices at least one of claims 21, 27 and 33 of the '301 patent.

Answer: Denied.

77. On information and belief, Defendants' nutritional supplements and/or multivitamins, including but not limited to, the CVS Private Label Products, now and in the past, are specifically made to be taken orally, are a material part of the method of at least one of claims 27 and 33 of the '301 patent, and are not staple articles nor commodities of commerce suitable for substantial non-infringing uses.

Answer: Denied.

78. At the very least, Defendants were, and/or their agents and contract manufacturers were, willfully blind as to the existence of the '301 patent, and/or willfully blinded itself to end users' direct infringement of the '301 patent as a result of end users' use of the CVS Private Label Products in a manner that follows the suggested use of the CVS Private Label Products, on the product labels, whereby the Defendants' instructions and promotional activities encourage, promote, instruct, and teach methods and uses, now and in the past, that meet at least the limitations of at least one of claims 21, 27 and 33 of the '301 patent.

Answer: Denied.

79. On information and belief, Defendants, and/or their agents and contract manufacturers, knew of the '301 patent, ignored and/or disregarded that their actions constituted infringement of a valid patent, and acted despite an objectively high likelihood that their actions constituted infringement of the '301 patent, and therefore Defendants' infringement is and has been willful, wanton, deliberate and without license, thereby rendering this case exceptional within the meaning of 35 U.S.C. §§ 284 and 285.

Answer: Denied.

80. Defendants' acts have caused and will continue to cause irreparable harm and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

Answer: Denied.

81. Unless preliminarily and permanently enjoined, Defendants' have and will continue to infringe the '301 patent to Plaintiffs' substantial and irreparable harm.

Answer: Denied.

COUNT V: INFRINGEMENT OF THE Re '480 PATENT

82. Plaintiffs reallege and incorporate herein by reference the preceding paragraphs as though fully set forth herein.

Answer: CVS incorporates herein by reference its responses to the preceding paragraphs as though fully set forth herein.

83. Defendants, among other things, make, have made for them, use, offer for sale, sell, market, promote, distribute and/or import within the United States, now and in the past, multivitamins and dietary supplements, such as, for example, products that contain chromium picolinate in combination with Biotin. Exemplary products made and/or sold by Defendants that include chromium picolinate in combination with Biotin, or its equivalent, include, but are

necessarily limited to, Spectravite Ultra Men's multivitamin, Spectravite Adult 50+ multivitamin, Spectravite Ultra Men's 50+ multivitamin, Spectravite Ultra Women's 50+ multivitamin (collectively the "Biotin Spectravite Products"), and CVS Diabetes Support Supplements (collectively the "CVS Private Label Biotin Products"). Discovery may uncover other products made, made for it, used, offered for sale, sold, distributed, marketed, promoted, and/or imported by the Defendants, now and in the past, that include chromium picolinate in combination with Biotin, or its equivalents, that may infringe the '480 patent. In addition, Defendants, among other things, have created and distributed, and continue to create and distribute suggested instructions for use, labels and marketing materials for such CVS Private Label Biotin Products, and have promoted the sale of and sold, now and in the past, and continue to promote the sale of and sell such CVS Private Label Biotin Products to end users and customers.

Answer: Denied.

84. On information and belief, Defendants, directly or indirectly through the actions of other entities, have infringed, now and in the past, and continue to infringe the Re '480 patent directly, indirectly (by inducing or contributing to the infringement by others), jointly, literally and/or equivalently, by, among other things, making, having made for it, using, marketing, distributing, selling, offering for sale, promoting, and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Biotin Products, that embody, and include instructions and product labels encouraging the practice of, at least one of claims 1, 10 and 11 of the Re '480 patent.

Answer: Denied.

85. On information and belief, Defendants have, and/or their agents and contract manufacturers have, infringed, now and in the past, and continue to infringe the Re '480 patent directly, jointly, literally and/or equivalently, by, among other things, making, having made for them, using, selling, distributing, marketing, promoting, offering for sale and/or importing into the United States, now and in the past, nutritional supplements and/or multivitamins, including, but not limited to, the CVS Private Label Biotin Products, which contain chromium picolinate in combination with Biotin, or its equivalent, that embody at least claim 10 of the Re '480 patent. Upon information and belief, Defendants have contract manufacturers and/or other agents make for them, and according to specifications known to and specified by them, the CVS Private Label Biotin Products, including the Biotin Spectravite Products that are sold to users as equivalent to and which are intended to match the active ingredients and dosage amounts in Centrum® brand multivitamins.

Answer: Denied.

86. Upon information and belief, end users and consumers take the CVS Private Label Biotin Products according to their suggested instructions of orally ingesting them. End users and customers have infringed, now and in the past, and continue to infringe at least one of claims 1, 10 and 11 of the Re '480 patent directly, jointly, literally and/or by equivalents by, among other things, orally taking and using the CVS Private Label Biotin Products in a manner that practices at least one of claims 1, 10 and 11 of the Re '480 patent.

Answer: CVS is without knowledge or information sufficient to admit or deny the allegations regarding end users' and consumers' ingestion, and denies the remaining allegations.

87. On information and belief, Defendants, and/or their agents and contract manufacturers, had and continue to have actual and constructive knowledge of and are aware of or willfully blind to the Patents-in-Suit, including the Re '480 patent. Plaintiffs have notified the industry of the Patents-in-Suit and its settlement of a patent infringement action with, and license of the Re '480 patent to, Pfizer for its Centrum® multivitamins on which the Spectravite Products are based and on which the Defendants direct consumers to compare to its Spectravite Products.

Answer: Denied.

88. With knowledge of the Re '480 patent and the specific intent to encourage, promote, instruct, contribute to and induce the infringement of the Re '480 patent, Defendants have infringed, now and in the past, and continue to infringe at least one of claims 1, 10 and 11 of the Re '480 patent, indirectly, jointly, literally and/or by equivalents, by, among other things, encouraging, promoting, instructing, teaching, contributing to and inducing end users and customers to infringe at least one of claims 1, 10 and 11 of the Re '480 patent by, among other things, (1) making, having made for them, using, offering for sale, selling, distributing, marketing and/or importing within the United States, now and in the past, the CVS Private Label Biotin Products, and (2) creating and distributing suggested instructions for use, labels and promotional advertising materials that Defendants knew and continue to know, encourages, promotes, instructs, teaches, contributes to and induces use of the CVS Private Label Biotin Products, now and in the past, in a manner that Defendants knew, and continue to know, practices at least claims 1, 10 and 11 of the Re '480 patent. For example, Defendants with knowledge of Re '480 patent, make, have made for them, distribute, market, promote, offer for

sale, sell and/or import into the United States, now and in the past, the CVS Private Label Biotin Products, and created, provided, and continue to create and provide, instructions for use to consumers for their CVS Private Label Biotin Products, and otherwise promote and market such products, now and in the past, such that customers and end users orally take and use these CVS Private Label Biotin Products according to Defendants' instructions in a manner that the Defendants knew, and continue to know, practices at least one of claims 1, 10 and 11 of the Re '480 patent.

Answer: Denied.

89. On information and belief, Defendants' nutritional supplements and/or multivitamins, including but not limited to, the CVS Private Label Biotin Products, now and in the past, are specifically made to be taken orally, are a material part of at least one of claims 1 and 11 of the Re '480 patent, and are not staple articles nor commodities of commerce suitable for substantial non-infringing uses.

Answer: Denied.

90. At the very least, Defendants were, and/or their agents and contract manufacturers were, willfully blind as to the existence of the Re '480 patent, and/or willfully blinded themselves to end users' direct infringement of the Re '480 patent as a result of the end users' use of the CVS Private Label Biotin Products in a manner that follows the suggested use of the CVS Private Label Biotin Products on the product labels, whereby the Defendants' instructions and promotional activities encourage, promote, instruct, and teach methods, now and in the past, that meet at least the limitations of at least one of claims 1, 10 and 11 of the Re '480 patent.

Answer: Denied.

91. On information and belief, Defendants, and/or their agents and contract manufacturers, knew of the Re '480 patent, ignored and/or disregarded that their actions constituted infringement of a valid patent, and acted despite an objectively high likelihood that their actions constituted infringement of the Re '480 patent, and therefore Defendants' infringement is and has been willful, wanton, deliberate and without license, thereby rendering this case exceptional within the meaning of 35 U.S.C. §§ 284 and 285.

Answer: Denied.

92. Defendants' acts have caused and will continue to cause irreparable harm and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

Answer: Denied.

93. Unless preliminarily and permanently enjoined, Defendants have and will continue to infringe the Re '480 patent to Plaintiffs' substantial and irreparable harm.

Answer: Denied.

DAMAGES AND RELIEF

94. Defendants' infringement of the Patents-in-Suit has caused Plaintiffs irreparable harm for which there is no adequate remedy at law.

Answer: Denied.

95. Furthermore, as a consequence of Defendants' infringement of the Patents-in-Suit, Plaintiffs have suffered damages in an amount not yet determined, and which will be determined at trial, for the infringement committed at least within six years prior to the filing of this Complaint, and any further damages for infringement committed after filing of the Complaint (the 'Damages Period'), and that at a minimum Plaintiffs are entitled to a reasonable royalty during the Damages Period.

Answer: Denied.

96. This is an exceptional case as that term is used in 35 U.S.C. § 285.

Answer: Denied.

PLAINTIFFS' PRAYER FOR RELIEF

CVS denies that Plaintiffs are entitled to any of the relief set forth in their "Prayer for Relief."

DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, CVS states the following defenses:

FIRST DEFENSE

1. Each purported claim for the relief in the First Amended Complaint is barred as against CVS Health Corporation for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

2. The claims of United States Patent Nos. 5,948,772, 6,136,317, 6,251,889, 6,143,301, and RE39,480 (collectively, the "Patents-in-Suit") are invalid because they fail to meet the requirements of patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

THIRD DEFENSE

3. CVS has not directly or indirectly infringed any valid claim of the Patents-in-Suit either literally or under the doctrine of equivalents.

FOURTH DEFENSE

4. Plaintiffs' claims are barred in whole or in part by one or more of the equitable doctrines of waiver, estoppel, implied license, laches, and/or unclean hands.

FIFTH DEFENSE

5. Plaintiffs lack standing to bring one or more claims to the extent they were not the sole owner of the Patents-in-Suit as of the filing of the Complaint.

SIXTH DEFENSE

6. Plaintiffs' claims for damages are statutorily limited, at least, by 35 U.S.C. §§ 286, 287, and/or 288.

SEVENTH DEFENSE

7. Plaintiffs are not entitled to equitable relief because they have an adequate remedy at law.

EIGHTH DEFENSE

8. Plaintiffs cannot prove this is an exceptional case under 35 U.S.C. § 285.

NINTH DEFENSE

9. Upon information and belief, Plaintiffs have engaged in patent misuse with one or more of the Patents-in-Suit, by tying the licensing of the Patents-in-Suit with the condition of purchasing a separable, staple good, so as to impermissibly broaden the scope of the Patents-in-Suit with an anticompetitive effect.

10. Plaintiffs' patent regarding a method of treatment using chromic tripicolinate, U.S. Patent No. 5,087,623 (the "'623 patent"), expired on February 11, 2009.

11. Nevertheless, even after Plaintiffs' '623 patent expired, Nutrition 21 admittedly "sells and continues to sell its Chromax® chromium picolinate product according to a business

policy and practice that grants its customers a limited license under Nutrition 21's patents to use Chromax® chromium picolinate in their products and for uses covered by the Patents-in-Suit."

12. Upon information and belief, and consistent with Plaintiffs' stated policy, Plaintiffs have tied the licensing of the Patents-in-Suit to the purchase of their Chromax® product, even though the patent covering the use of that product expired in 2009.

13. Plaintiffs' Chromax® chromium picolinate product is a staple product, used outside of the scope of the Patents-in-Suit.

14. By requiring entities to purchase Chromax® in order to obtain a license to the Patents-in-Suit, Plaintiffs seek to compel the purchase of their chromium picolinate and thereby expand the scope the Patents-in-Suit, along with attempting to recapture material included in the expired '623 patent.

15. The Patents-in-Suit do not claim chromium picolinate but rather claim the combination of chromium picolinate with certain other ingredients.

16. Upon information and belief, Plaintiffs have market power in the market for the tying patent and products, specifically the Patents-in-Suit and the products that practice the Patents-in-Suit as alleged by Plaintiffs, through their licenses to the other entities described in their Complaint.

17. Upon information and belief, by requiring licensees to the Patents-in-Suit to purchase Chromax®, Plaintiffs have caused a reduction in competition that has reduced consumer choice, restrained output, and raised prices.

TENTH DEFENSE

18. The Re '480 patent issued on January 23, 2007 and is a reissue of U.S. Patent No. 5,929,066, which issued on July 27, 1999. Plaintiffs' infringement claims regarding the Re '480 patent are barred, in whole or in part, under 35 U.S.C. § 252 by the doctrine of intervening rights.

ELEVENTH DEFENSE

19. Plaintiffs' claims and allegations are barred under the doctrines of equitable estoppel, res judicata and/or issue preclusion by this Court's prior rulings in the *Pfizer* litigation (*JDS Therapeutics, LLC v. Pfizer Inc.*, C.A. No. 12-9002 (S.D.N.Y.)).

RESERVATION OF DEFENSES

20. CVS reserves the right to add any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff CVS Pharmacy, Inc. ("CVS"), brings the following counterclaims against Plaintiffs/Counterclaim-Defendants JDS Therapeutics, LLC and Nutrition 21, LLC (collectively "Plaintiffs" or "Counterclaim-Defendants"), and avers as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of the counterclaims under 28 U.S.C. §§ 2201, 2202, 1331, and 1338 in that the claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act.

2. The Court has personal jurisdiction over Counterclaim-Defendants by virtue of their filing and prosecuting this action against CVS in this judicial district.

3. Venue for adjudication of these counterclaims is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

PARTIES

4. CVS Pharmacy, Inc. (“CVS Pharmacy” or “CVS”) is a wholly-owned subsidiary of CVS Health, and is a corporation organized under the laws of Rhode Island having a principal place of business in Woonsocket, Rhode Island.

5. Upon information and belief, and based on Counterclaim-Defendants’ Complaint, JDS Therapeutics, LLC (“JDS”) is a limited liability company organized under the laws of Delaware, having a principal place of business in Purchase, New York.

6. Upon information and belief, and based on Counterclaim-Defendants’ Complaint, Nutrition 21, LLC (“Nutrition 21”) is a limited liability company organized under the laws of New York, having a principal place of business in Purchase, New York. Nutrition 21 is a wholly-owned subsidiary of JDS.

NATURE OF THE ACTION

7. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202, because this case is based on a case of actual controversy within the Court’s jurisdiction seeking a declaratory judgment that CVS has not infringed any valid claim of United States Patent Nos. 5,948,772, 6,136,317, 6,251,889, 6,143,301, and RE39,480 (collectively, the “Patents-in-Suit”), and that the Patents-in-Suit are invalid and/or unenforceable.

BACKGROUND

9. United States Patent No. 5,948,772 (“the ‘772 patent”), states on its face that it is titled “Chromium Picolinate Compositions and Uses Thereof” and issued on September 7, 1999.

10. On information and belief, and based on Counterclaim-Defendants' Complaint, the '772 patent is jointly owned by Counterclaim-Defendants.

11. United States Patent No. 6,136,317 ("the '317 patent"), states on its face that it is titled "Chromium Picolinate Compositions" and issued on October 24, 2000.

12. On information and belief, and based on Counterclaim-Defendants' Complaint, the '317 patent is jointly owned by Counterclaim-Defendants.

13. United States Patent No. 6,251,889 ("the '889 patent"), states on its face that it is titled "Chromium Picolinate Compositions" and issued on June 26, 2001.

14. On information and belief, and based on Counterclaim-Defendants' Complaint, the '889 patent is jointly owned by Counterclaim-Defendants.

15. United States Patent No. 6,143,301 ("the '301 patent"), states on its face that it is titled "Chromium Picolinate Compositions and Uses Thereof" and issued on November 7, 2000.

16. On information and belief, and based on Counterclaim-Defendants' Complaint, the '301 patent is jointly owned by Counterclaim-Defendants.

17. United States Reissue Patent No. 39,480 ("the Re '480 patent"), states on its face that it is titled "Chromium/Biotin Treatment of Type II Diabetes" and issued on January 23, 2007.

18. On information and belief, and based on Counterclaim-Defendants' Complaint, the Re '480 patent is jointly owned by Counterclaim-Defendants.

COUNT I
(Declaration of Invalidity of the '772 Patent)

19. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

20. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, validity of the '772 patent.

21. The claims of the '772 patent are invalid for failure to meet one or more of the requirements for patentability, including, but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

22. One or more of the claims of the '772 patent is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or obvious in view of disclosures in the prior art, including but not limited to: U.S. Patent No. 5,087,623 and EP0514451 (WO 91/11117).

23. CVS is entitled to a judicial declaration that the '772 patent is invalid.

COUNT II
(Declaration of Non-Infringement of the '772 Patent)

24. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

25. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, infringement of any valid claim of the '772 patent.

26. CVS has not directly or indirectly infringed any valid claim of the '772 patent either literally or under the doctrine of equivalents.

27. CVS is entitled to a judicial declaration that it does not directly or indirectly infringe any valid claim of the '772 patent either literally or under the doctrine of equivalents.

COUNT III
(Declaration of Invalidity of the '317 Patent)

28. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

29. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, validity of the '317 patent.

30. The claims of the '317 patent are invalid for failure to meet one or more of the requirements for patentability, including, but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

31. One or more of the claims of the '317 patent is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or obvious in view of disclosures in the prior art, including but not limited to: U.S. Patent No. 5,087,623 and EP0514451 (WO 91/11117).

32. CVS is entitled to a judicial declaration that the '317 patent is invalid.

COUNT IV
(Declaration of Non-Infringement of the '317 Patent)

33. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

34. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, infringement of any valid claim of the '317 patent.

35. CVS has not directly or indirectly infringed any valid claim of the '317 patent either literally or under the doctrine of equivalents.

36. CVS is entitled to a judicial declaration that it does not directly or indirectly infringe any valid claim of the '317 patent either literally or under the doctrine of equivalents.

COUNT V
(Declaration of Invalidity of the '889 Patent)

37. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

38. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, validity of the '889 patent.

39. The claims of the '889 patent are invalid for failure to meet one or more of the requirements for patentability, including, but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

40. One or more of the claims of the '889 patent is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or obvious in view of disclosures in the prior art, including but not limited to: U.S. Patent No. 5,087,623 and EP0514451 (WO 91/11117).

41. CVS is entitled to a judicial declaration that the '889 patent is invalid.

COUNT VI
(Declaration of Non-Infringement of the '889 Patent)

42. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

43. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, infringement of any valid claim of the '889 patent.

44. CVS has not directly or indirectly infringed any valid claim of the '889 patent either literally or under the doctrine of equivalents.

45. CVS is entitled to a judicial declaration that it does not directly or indirectly infringe any valid claim of the '889 patent either literally or under the doctrine of equivalents.

COUNT VII
(Declaration of Invalidity of the '301 Patent)

46. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

47. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, validity of the '301 patent.

48. The claims of the '301 patent are invalid for failure to meet one or more of the requirements for patentability, including, but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

49. One or more of the claims of the '301 patent is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or obvious in view of disclosures in the prior art, including but not limited to: U.S. Patent No. 5,087,623 and EP0514451 (WO 91/11117).

50. CVS is entitled to a judicial declaration that the '301 patent is invalid.

COUNT VIII
(Declaration of Non-Infringement of the '301 Patent)

51. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

52. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, infringement of any valid claim of the '301 patent.

53. CVS has not directly or indirectly infringed any valid claim of the '301 patent either literally or under the doctrine of equivalents.

54. CVS is entitled to a judicial declaration that it does not directly or indirectly infringe any valid claim of the '301 patent either literally or under the doctrine of equivalents.

COUNT IX
(Declaration of Invalidity of the Re '480 Patent)

55. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

56. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, validity of the Re '480 patent.

57. The claims of the Re '480 patent are invalid for failure to meet one or more of the requirements for patentability, including, but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and 282 and/or for improper double patenting.

58. One or more of the claims of the Re '480 patent is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or obvious in view of disclosures in the prior art, including but not limited to: U.S. Patent No. 5,087,623 and EP0514451 (WO 91/11117).

59. CVS is entitled to a judicial declaration that the '480 patent is invalid.

COUNT X
(Declaration of Non-Infringement of the Re '480 Patent)

60. CVS repeats and incorporates by reference Paragraphs 1 to 18 of its Counterclaims as if fully set forth herein.

61. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between CVS and Counterclaim-Defendants regarding, *inter alia*, infringement of any valid claim of the Re '480 patent.

62. CVS has not directly or indirectly infringed any valid claim of the Re '480 patent either literally or under the doctrine of equivalents.

63. CVS is entitled to a judicial declaration that it does not directly or indirectly infringe any valid claim of the Re '480 patent either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, CVS prays that this Court enter judgment:

- A. Dismissing the First Amended Complaint with prejudice and denying each and every prayer for relief contained therein.
- B. Declaring the claims of the '772 patent invalid and/or not infringed.
- C. Declaring the claims of the '317 patent invalid and/or not infringed.
- D. Declaring the claims of the '889 patent invalid and/or not infringed.

- E. Declaring the claims of the '301 patent invalid and/or not infringed.
- F. Declaring the claims of the Re '480 patent invalid and/or not infringed.
- G. Declaring that this case is “exceptional” within the meaning of 35 U.S.C. § 285.
- H. Awarding all costs and expenses of this action, including reasonable attorneys’ fees, to CVS.
- I. Awarding to CVS such further relief as this Court may deem necessary, just, or proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, CVS hereby requests a trial by jury for all issues so triable.

Respectfully submitted,

Dated: July 20, 2015

By: /s/ Steven Lieberman
Steven Lieberman
Rothwell, Figg, Ernst & Manbeck, P.C.
607 14th St., N.W., Suite 800
Washington, DC 20005
Phone: 202-783-6040
Facsimile: 202-783-6031
E-Mail: slieberman@rfem.com

*Counsel for Defendants CVS Health
Corporation and CVS Pharmacy, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 20TH of July, 2015, the foregoing **DEFENDANTS' ANSWER AND CVS PHARMACY, INC.'S COUNTERCLAIMS TO FIRST AMENDED COMPLAINT** was filed electronically by means of the Court's CM/ECF system. I further certify that the foregoing was served by means of electronic mail, as well as by the Court's CM/ECF system, which should have sent a Notice of Docket Activity, upon the following counsel of record for Plaintiff:

Brian M. Rothery
Joseph Diamante
Madelon Lys Witte
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, NY 10036-2711
(212)-806-6205
Fax: (212)-806-9205
brothery@stroock.com
jdiamante@Stroock.com
mwitte@stroock.com

/s/ Nasri V. B. Hage
Nasri V. B. Hage